Dockets Management Branch (HFA-305) FDA 5630 Fishers Lane, Rm. 1061 Rockville, MD 30857

April 5, 1999

Att'n: Michael Friedman, M.D. Lead Deputy Commissioner 7826 '99 APR 19 A8:47

Dear Dr. Friedman:

We are writing in regard to the proposed rules on structure/function claims, 21 CFR, Part 101, Docket #98-0044. As it stands, we are utterly opposed to it.

We are <u>not</u>, however, opposed to the DSHEA, adopted by Congress, and support especially Section 6. But we are objecting to certain regulations the FDA and the drug companies are proposing, specifically bearing on:

- 1. Any restrictions on our ability to take care of our own health, including preventive measures, particularly by the redefintion of disease. This would nullify DSHEA's rule regarding a product's right to make structure and function claims on the label.
- 2. Any limit on our access to information about dietary supplements, whether it meets your definition of "scientific" or otherwise.

We each have one life to live, one body to take care of, and we do not wish to hand over that responsibility to the medical or pharmaceutical interests, mainly because their viewpoints and actions, unfortunately, are too often based on other than the public welfare. To care for ourselves in the best way, we need <u>all</u> information to be accessible, easily and freely, without censorship by the FDA.

Your intentions may be good but the road to hell...etc. Please allow us the freedom to decide for ourselves how to take care of ourselves--no Big Brother or Big Daddy needed here.

Sincerely,

Lila and Irwin Berman

Tirwin Berman

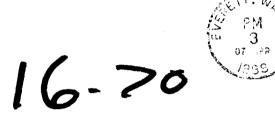
Lila Germa

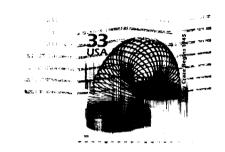
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ATT'N:
Michael Friedman, M.D.
Lead Deputy Commissioner

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